

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Paul T. Jacobs et al.

Serial No.: 08/120,303

Art Unit: 1809

Filed : September 13, 1993

Examiner: J. Warden

: METHOD AND DEVICE FOR VAPOR
STERILIZATION ARTICLES HAVING LUMENS#27
OK'd

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Joseph F. Shirtz

Name of applicant, assignee, or Registered Representative

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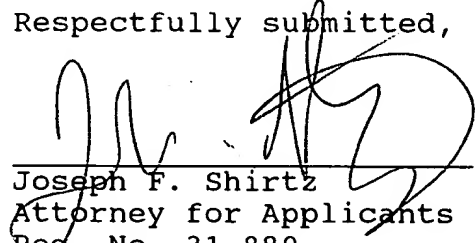
Hon. Commissioner of Patents
and Trademarks
Washington, D. C. 20231

GROUP 1800

Dear Sir:

Enclosed are three copies of a Reply Brief To New Grounds Of
Rejection in the above-captioned matter. The Commissioner is
hereby authorized to charge any additional fees which may be
required to Account No. 10-0750/JJM-85/JFS. This Authorization is
being submitted in triplicate.

Respectfully submitted,


Joseph F. Shirtz
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DATED: May 4, 1995





JJM-85

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Paul T. Jacobs et al.

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For : METHOD AND DEVICE FOR VAPOR STERILIZATION
ARTICLES HAVING LUMENS

#27
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Assistant Commissioner for Patents
Washington, D.C. 20231

REPLY BRIEF TO NEW GROUNDS OF REJECTION

Dear Sir:

Further to and in response to the Examiner's Answer dated March
9, 1995, Appellants hereby reply to the New Grounds of Rejection
provided in the Examiner's Answer.

Claims 11 and 19-20 have been rejected under 35 USC §102(e) as being anticipated by Al-Sioufi. It is axiomatic that in order for a §102 novelty objection to stand, every element of the claimed invention must be shown in the cited reference. The Al-Sioufi reference fails to show much of the structure claimed in Claim 11 of the present application. There is required means for connecting an opening of a vessel to a lumen in order to provide the device with the stated function of delivering antimicrobial vapor to such a lumen of an article during solution vapor sterilization. Clearly, this structure is missing.

The Examiner has cited Figure 1 of the reference and certain associated descriptions. There is no means for connection of a lumen. Thus, the structure is lacking to perform the function of the means plus function portion of Claim 11. That portion states that the device delivers antimicrobial vapor to the lumen of an article during solution vapor sterilization. The reference cited teaches directly away from such a structure in the language cited by the Examiner. It clearly states that "it is frequently the case that these tubes are provided with a partial vacuum and a double-ended hollow syringe needle placed in the stopper end so that blood samples can be drawn directly from the donor into the tube using the vacuum in the tube." Column 7, lines 28 et. seq. This device can not be said to be delivering antimicrobial vapor in any way or form. If, in fact, the device does contain an antimicrobial solution, such a solution would not be delivered to a lumen if the internal atmosphere of the device is under a vacuum as indicated in the specific language of the reference.

Furthermore, there is no connection of the device to a lumen and no means to connect such a device to a lumen for antimicrobial delivery during a solution vapor sterilization process. The rejection has hypothesized certain modifications that can be made to attach the device to a lumen. However, none of these are

reasonable hypothecations nor are they disclosed in the reference. Thus, the reference does not support a 35 USC §102 rejection.

Claim 20 also distinguishes from this reference. Claim 20 calls for "means for connecting said vessel to the end of said lumen to provide antimicrobial vapor directly to the lumen during the solution vapor sterilization". Such a means is not found in the cited reference. There is no means for connecting a vessel to the end of a lumen such that the function of the means is carried out. Means plus functional language encompasses means for carrying out that function. In this case there is no disclosure of any attachment means for delivering antimicrobial solution directly to a lumen during a solution vapor sterilization cycle. Nor could the closed caps of Figure 1 of the reference (as cited by the Examiner) perform such function. Some modification must be made in order to provide the missing element of an attachment means for attaching the tube of reference to a lumen for vapor sterilization.

Similarly, Claims 11 and 19-20 have been rejected under 35 USC §102(b) as being anticipated by or obvious over the Fisher Scientific Catalog.

The Fisher Scientific Catalog merely shows bottles containing solutions of hydrochloric acid and sodium hydroxide. The Examiner in his rejection argues that the hydrochloric acid is a known quantity of antimicrobial solution and one could attach these bottles to a lumen. However, there is no disclosure of a structure to provide the means plus function claim limitation of either Claim 11 or Claim 20 of the present application. These claims specifically call for means for connecting the opening of the vessel to a lumen. The presence of screw threads on the end of a bottle for containing acid do not satisfy this limitation absent some adaptor permitting the attachment through use of these threads to a lumen. Therefore, this limited disclosure can not be said to anticipate the claims of the present application.

Similarly, the Fisher Scientific reference fails to provide basis for 35 USC §103 obviousness rejection. There is no teaching, there is no suggestion, there is no hint of attachment of the containers shown in the catalog to a lumen for antimicrobial vapor delivery during a solution vapor sterilization process. There is no means provided for attaching such containers to such lumens. The rejection states that the portion enabling the attachment of a removable closure cap as depicted in the Figure would further have inherently provided a capability of connecting the opening of the container to a lumen. There is no teaching or suggestion that such a structure is capable of providing the limitation of the means plus function language of either Claim 11 or Claim 20. The shear size of the opening provided for in the bottle shown in the Fisher Scientific catalog, as determinable by the presence of the beaker and pipette in one photograph, included in the reference shows that such openings would not be attachable to a lumen (as commonly used to indicate a long narrow bore).

The Fisher Scientific catalog can not therefore be said to teach the structure of providing means for connecting a container containing a known quantity of antimicrobial solution to a lumen for delivering antimicrobial vapor to the lumen during vapor sterilization.

Finally, Claims 11 and 18-20 have been rejected under 35 USC §102(b) as anticipated by or in the alternative under 35 USC §103 as obvious over Engel '434. The Engel device does not provide any teaching or suggestion of an attachment to a lumen or an attachment mechanism for attachment to a lumen. Rather it discloses a device which contains an expandable foam and which is impregnated with a volatile solution. It is accepted that this volatile solution may be antimicrobial and may be in known quantity. However, the only teaching of the reference is that once the cap is removed from the device, this foam substance expands in order to aid in the volatilization of the solution present within the container. There

is no teaching or suggestion of attachment of the device to a lumen nor is there a lumen present within the reference to provide some hint of a structure which meets the limitation of "means for connecting said opening of said vessel to said lumen". Thus, the Engel reference also fails to teach the subject matter of Claim 11.

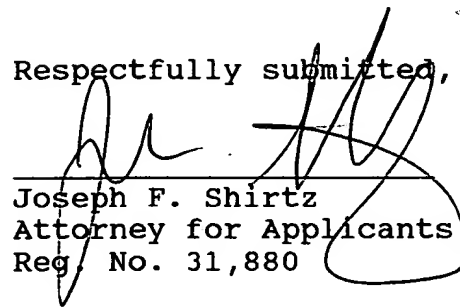
Similarly, Claim 20 contains the limitation of "means for connecting said vessel to the end of said lumen to provide antimicrobial vapor directly to the lumen during solution vapor sterilization". There is no teaching of a means capable of this. The Engel reference requires that the foam be expandable. There is no teaching of a structure for attachment of the Engel device to a lumen which would further permit the foam to expand in order to deliver the antimicrobial solution to a lumen during a vapor sterilization cycle.

In addition to the above-described reasons, it is clear from the statute that when using means plus function language the structures disclosed within the application must be reviewed as the structure is intended. The range of equivalents is determined as the equivalents associated with those structures. None of the references cited show the structures included in the application to support the means plus function language of the claims. None of the references cited show an equivalent to such structures. None of the references show a structure which is directed to or indicated as usable for attachment to lumens during vapor sterilization cycles. Although this is an intended use of the product it is a limitation insofar as the means plus function language must be interpreted in light of that intended use as shown in the specification.

For the above described reasons, it is respectfully submitted that the claims of the present application are fully allowable over the references cited by the Examiner both in the underlying Office Action and in the New Grounds of Rejection provided in the

Examiner's Answer. Reversal of the Examiner and allowance of the claims is respectfully requested.

Respectfully submitted,



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